

## Non Serious Adverse Drug Reactions Report

Start Date:2014-10-30 End Date:2014-11-02

|   |                   |  |  |                                  |                            |                                   |                     |
|---|-------------------|--|--|----------------------------------|----------------------------|-----------------------------------|---------------------|
| <b>Study</b><br>:EMR200583-500  |                   | <b>Investigator</b> :NA                  |  | <b>Country of Investigator</b> : |                            | <b>SiteNo</b> :014                |                     |
| <b>Subject No</b> :014 0001   |                   | <b>Subject Initials</b> :xx              | <b>DOB</b> :                           | <b>Sex</b> :Male                 | <b>Race</b> :              | <b>Height</b> :170cm              | <b>Weight</b> :72kg |
| <b>First administration date of batch</b> :                                   |                   |  |  | <b>Batch number</b> :            |                            |                                   |                     |
| <b>Study Drug</b>   |                   | <b>Start Date</b>                        |  | <b>Dose</b>                      |                            | <b>Change in Dose</b>             |                     |
| Bisoprolol  |                   | 09/04/2014                               |  | 5mg                              |                            |                                   |                     |
| ASA   |                   | 09/04/2014                               |  | 75mg                             |                            |                                   |                     |
| <b>Adverse Event</b>  | <b>Start Date</b> | <b>End Date</b>                          | <b>Time related to study treatment</b> | <b>Causality to study drug</b>   | <b>Severity</b>            |                                   |                     |
|   |                   |  |  |                                  |                            |                                   |                     |
| <b>Causality Factors</b>  |                   | <b>Action Taken with Study Treatment</b> | <b>Other action taken</b>              | <b>Outcome</b>                   | <b>AE Special Interest</b> | <b>AE dose limiting toxicity</b>  |                     |
|   |                   |  |  |                                  |                            |                                   |                     |
| <b>Event description:</b>   |                   |  |  |                                  |                            |                                   |                     |
| <b>Subject received concomitant medications:</b> No                           |                   |  |  |                                  |                            |                                   |                     |
| <b>Does the subject have any relevant past or present medical conditions:</b> |                   |  |  |                                  |                            |                                   |                     |
| <b>Condition</b>  |                   |  |  | <b>Start Date</b>                |                            | <b>Related to study condition</b> | <b>Ongoing</b>      |
| Cardiovascular Diseases(hypertension, )                                       |                   |  |  |                                  |                            |                                   |                     |
| Diabetes mellitus type 2(type 2)  |                   |  |  |                                  |                            |                                   |                     |
|   |                   |  |  |                                  |                            |                                   |                     |

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